



Southern Bone & Joint Center Associates

A PROFESSIONAL CORPORATION

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FDA Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs:

In relationship to the FDA proposal to regulate allograft tissue, it is my professional opinion that we as orthopaedic surgeons have used this device for a long period of time without ill effects to the patients. We know that the allograft tissue provided to us by the different bone banks in Texas have done a very good job certifying that the bone graft is sterile and has been tested for different possibilities of cross infection. In my professional opinion, all my patients that have been using allograft as bone tissue either for cervical or for lumbar fusions have done well and have had no ill effects from the usage of such devices. Some newer bone grafts that have been machined, like Dower's for the interbody fusion and for the posterolateral interbody fusion as cortical bone, have also been doing very well without ill effects.

It is my professional opinion that such allograft regulations should be left to the different bone banks that have been doing a very good job so far.

Sincerely yours,

Jorge E. Tijmes, M.D.

JET/xg

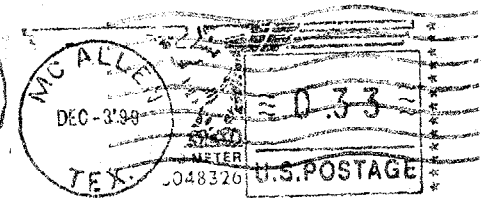
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